DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2014

Origami Surgical, LLC
% Mr. John Gillespie
Clover Medical, LLC
79 Haven Street
Dover, Massachusetts 02030

Re: K142639
Trade/Device Name: StitchKit® Suture Delivery Canister with Polypropylene Surgical Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW, GCJ, NAY
Dated: September 22, 2014
Received: September 23, 2014

Dear Mr. Gillespie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142639

Device Name
StitchKit® Suture Delivery Canister with Polypropylene Surgical Suture

Indications for Use *(Describe)*
StitchKit® Suture Delivery Canister with Polypropylene Surgical Suture facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. It contains polypropylene surgical suture indicated for use in general soft tissue approximation and/or ligation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter: Origami Surgical, LLC

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Phone: 1-973-765-6256

Fax Number: 1-973-695-1045

Email: origamisurgical@gmail.com

Contact Person: John Gillespie (consultant)

Phone: 1-973-765-6256

Fax Number: 1-973-695-1045

Email: origamisurgical@gmail.com

Date of Preparation: September 15, 2014

Device Trade Name: StitchKit® Suture Delivery Canister with Polypropylene Surgical Suture

Common Name: Suture Delivery Canister containing suture, non-absorbable, synthetic, Polypropylene

Classification: Class: II

Panel: General and Plastic Surgery

Regulation: **876.1500** Endoscopes & Accessories

Product Code: **GCJ** Lap'scope, Gen'l & Plastic Surgery

Regulation: **876.1500** Endoscope and Accessories

Product Code: **NAY** (System, Surgical, Computer Controlled Instrument)

Regulation: **878.5010** Nonabsorbable polypropylene surgical suture

Product Code: **GAW** Nonabsorbable polypropylene surgical suture.

Legally Marketed Devices to Which the Device is Substantially Equivalent:

K123811: StitchKit® Suture Delivery Canister with ePTFE Surgical Suture

K133356: Prolene® Polypropylene Surgical Suture

Description of Device:

The StitchKit® Suture Delivery Canister with Polypropylene Surgical Suture ("StitchKit") is a sterile, single-use plastic canister that is pre-loaded with multiple strands of legally marketed monofilament polypropylene surgical suture (with needles attached). The device facilitates robotic-assisted endoscopic surgery by introducing these multiple strands of suture to the surgical field all at once. The surgeon can then dispense the suture strands one at a time. The device is sized to be passed through a ≥12 mm trocar. As suturing is completed with each strand, used needles are deposited into a compartment within the StitchKit® canister. Once the surgeon has finished suturing, the device is removed along with the used needles inside. It is supplied sterile in a plastic tray with Tyvek® lid.

Indications for Use:

StitchKit® Suture Delivery Canister with Polypropylene Surgical Suture facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. It contains polypropylene surgical suture indicated for use in general soft tissue approximation and/or ligation.

Summary of Technological Characteristics vs. Predicate:

The only significant difference in technological characteristics versus the primary predicate is the different suture material within the device (ePTFE vs. polypropylene). The suture within the proposed device is equivalent to the second predicate, polypropylene surgical suture.

Performance Data

The performance testing performed for this device includes:

☐ Suture testing including USP knot pull testing, diameter, and needle attachment

☐ Suture dispensing force testing

☐ Shelf life testing

☐ Physicochemical extraction testing & LAL Pyrogen testing

The predicate StitchKit® device was subjected to biocompatibility testing to support the original StitchKit® 510(k), K123811, and that testing applies to this StitchKit® version since the only change is the new legally marketed suture.

The proposed device was included in the sterilization validation included in the original 510(k), K123811, and there are no changes related to sterilization.

Conclusion

Based on the Indication for Use, technological characteristics, test data, and comparison to its predicate devices we conclude that the proposed StitchKit® device has been shown to be substantially equivalent to its predicate devices and is safe and effective for its intended use.